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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,615	04/20/2007	Yuzuru Umeda	1691-0217PUS1	4241

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EXAMINER

KASTURI, SRIRAM

ART UNIT	PAPER NUMBER
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1612

NOTIFICATION DATE	DELIVERY MODE
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07/25/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/574,615	Applicant(s) UMEDA ET AL.	
	Examiner SRIRAM KASTURI	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4-5-06, 7-5-06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-14 are pending.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13 and 14 are drawn for the use of composition for treating tear dysfunction, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 13 and 14 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Applicants claim an ophthalmic composition containing 3-hydroxybutyric acid and a method to treat tear dysfunction.

1. Claims 1-14 are rejected under 35 U.S.C. 102(b) as being anticipated by teachings of Chen et al (5,116,868)

Chen et al teachings include ophthalmic irrigating solution composition containing β -hydroxybutyrate at 10 mM concentration (Col.4, Table 2 line 44). Their teachings include use of D-isomer of β -hydroxybutyrate as a preferred component of the ophthalmic irrigation solution because only D-isomer is utilized in the cells (Col. 5, lines 66-68). Their teachings also clearly indicate that this irrigation composition is also particular importance to the cornea, and cornea obtains its nourishment from tear. Thus this composition has important role in maintenance of tear function (Col.1, lines 34-38). Their use of β -hydroxybutyrate at 10 mM (Col.4, Table 2 line 44) concentration is equivalent to 10 mMoles/litre which is within the range of 0.8 to 800 mmol/l as claimed by applicants (Claims 10 and 11).

2. Claims 1-14 are rejected under 35 U.S.C. 102(b) as being anticipated by teachings of Yoneda et al (US 6,495,598 B1).

Yoneda et al teach a preparation of irrigating solution containing D-3-hydroxybutyric acid for ocular surgery of cataract. They also claim it is excellent in the protection of ophthalmic tissues and endothelial cells during and after the operation and has a high in vivo stability (Abstract). Their teachings indicate that their irrigating solution is suitable for protecting intraocular tissues, and also prevents the surface of the corneal epithelium and the *conjunctiva* from *drying* in order to perform the surgery safely and

Art Unit: 1612

effectively (Col.1, lines 10-15). Thus they clearly indicate use of their irrigating ophthalmic composition containing D-3-hydroxybutyric acid is useful for treating keratoconjunctiva which is a disease of conjunctiva and drying that results due to tear dysfunction.

Additionally they confirm that D-form isomer of 3-HBA is the most effective among the D-form, D,L-form and L-form isomers (Col.6, Example 3, lines 57-60). Their teachings include use of D-3-hydroxybutyric acid (D-3-HBA) at 20 mM in their example 7 of their ophthalmic composition (Table 2) (Col.8 lines 45-60). This concentration of 20 mM of D-3-HBA is equivalent to 20 mmoles/litre which is within the range of 3-hydroxybutyric acid in the composition claimed by applicants (Claims 10 and 11). Additionally Yoneda et al teach use of their irrigating composition containing D-3-hydroxybutyric acid for ocular surgery in the eyes of rabbits (Col.5, lines 35- 38). Thus they clearly indicate a treatment method for tear dysfunction as claimed by applicant (Claim 12).

3. Claims 1-14 are rejected under 35 U.S.C. 102 (a) or (b) as being anticipated by teachings of Tomoko et al (JP 2003-313123). Tomoko et al teach a composition for preventing and or treating ophthalmopathy caused by apoptosis. Their teachings include use of 3-hydroxybutyric acid and/or its salt as an active ingredient for treating keratoconjunctivitis (Abstract). Their teachings include use of 3-hydroxybutyric acid at the concentration of 0.5 to 500 mmol/L as being claimed by applicants (Claims 10 and 11). They do teach using 1-3 drops of their 3-hydroxybutyric acid containing ophthalmic composition per time for the patient about several times per day. (Paragraph 0026, lines 2 and 3).

Priority papers of continuing data based on 371 of PCT/JP04/14774 dated 9-30-04 and foreign application JAPAN 2003-346858 are in Japanese. Hence the filing date of 4-20-07 is considered as priority date for this app. This Rejection will be reconsidered based on the submission of English translation of priority papers.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

Art Unit: 1612

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art.

Applicants claim an ophthalmic composition containing 3-hydroxybutyric acid and a method to treat tear dysfunction.

1. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over teachings of Chen et al (5,116,868) or Tomoko et al (JP 2003-313123)

Chen et al or Tomoko et al teachings indicate use of D-3-hydroxybutyric acid in their ophthalmic composition as indicated above in the instant office action. Their teachings indicate a method for treating tear dysfunction by using an effective amount of their composition as eye drops.

Based on prior art teachings of Chen et al, and Tomoko et al as explained above an artisan of ordinary skill in the art can prepare and use ophthalmic composition containing D-3-hydroxybutyric acid at 10-20 mmoles/litre for treating tear dysfunction and maintain keratoconjunctiva at normal state as set forth above in the instant office action. Thus there is reasonable expectation of success in preparing and using an ophthalmic composition containing D-3-hydroxybutyric acid.

Conclusion:

Claims 1-14 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SRIRAM KASTURI whose telephone number is (571)270-5263. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sriram Kasturi/
Examiner
/Gollamudi S Kishore, Ph.D/

Primary Examiner, Art Unit 1612